



DEC 3 1988

Re: Duromedics Cardiac Valve
Prosthesis
Docket No. 86E-0460

#12

The Honorable Donald J. Quigg
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks
Washington, DC 20231

Dear Commissioner Quigg:

This is in regard to the application for patent extension for U.S. Patent No. 4,328,592, filed by Hemex, Inc., under 35 U.S.C. 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for the Duromedics Cardiac Valve Prosthesis, the medical device claimed by the patent.

The total length of the review period for the Duromedics Cardiac Valve Prosthesis is 866 days. Of this time, 652 days occurred during the testing phase and 214 days occurred during the approval phase. The periods of time were derived from the following dates:

1. The date on which a clinical investigation was begun:
April 19, 1984.

FDA has verified the applicant's claim that a clinical investigation for the product was begun on April 19, 1984.

2. The date an application was initially submitted under section 515 of the Federal Food, Drug, and Cosmetic Act:
January 29, 1986.

The applicant claims the premarket approval application (P850006) was initially submitted on February 4, 1985. However, the application did not contain sufficient information to permit substantive review by FDA until receipt of an amendment on January 29, 1986.

3. The date the application was approved: August 29, 1986.

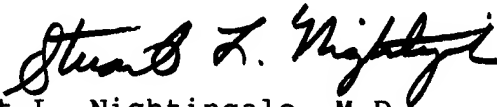
FDA has verified the applicant's claim that P850006 was approved on August 29, 1986.

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This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

A handwritten signature in dark ink, appearing to read "Stuart L. Nightingale". The signature is fluid and cursive, with the first name "Stuart" being the most prominent.

Stuart L. Nightingale, M.D.
Associate Commissioner
for Health Affairs

cc: James J. Schumann
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